DEPARTMENT OF HOMELAND SECURITY

U.S. Customs and Border Protection

Notice of Issuance of Final Determination Concerning Electroencephalogram (EEG) Cutaneous Electrodes


ACTION: Notice of final determination.

SUMMARY: This document provides notice that U.S. Customs and Border Protection (“CBP”) has issued a final determination concerning the country of origin of Rhythmlink International, L.L.C.’s, Electroencephalogram (EEG) Cutaneous Electrodes. Based upon the facts presented, CBP has concluded in the final determination that the last substantial transformation of the Electroencephalogram (EEG) Cutaneous Electrode Product occurs in the United States.

DATES: The final determination was issued on May 24, 2019. A copy of the final determination is attached. Any party-at-interest, as defined in 19 CFR 177.30, provides that notice of final determinations shall be published in the Federal Register within 60 days of the date the final determination is issued. Section 177.30, CBP Regulations (19 CFR 177.30), provides that any party-at-interest, as defined in 19 CFR 177.22(d), may seek judicial review of a final determination within 30 days of publication of such determination in the Federal Register.

Dated: May 24, 2019.

CRAIG T. CLARK,
Acting Executive Director, Regulations and Rulings, Office of International Trade.

HQ H300745
May 24, 2019

OT:RR:CTF:VS H300745 RSD

CATEGORY: Origin

David S. Robinson
Nexsen Pruet, PLLC
4141 Parklake Avenue
Suite 200
Raleigh, NC 27612

RE: U.S. Government Procurement; Title III, Trade Agreements Act of 1979 (19 U.S.C. § 2511); Subpart B, Part 177, CBP Regulations; Electroencephalogram (EEG) Cutaneous Electrodes; Substantial Transformation

Dear Mr. Robinson:

This is in response to your letter, dated September 10, 2018, requesting a final determination on behalf of Rhythmlink International, LLC. (Rhythmlink) pursuant to subpart B of Part 177 of the U.S. Customs and Border Protection (CBP) Regulations (19 C.F.R. Part 177).

This final determination concerns the country of origin of the Electroencephalogram (EEG) Cutaneous Electrodes which may be offered to the United States Government under an undesignated government procurement contract. This final determination, in HQ H300745, was issued at the request of Rhythmlink International, L.L.C. under procedures set forth at 19 CFR part 177, subpart B, which implements Title III of the Trade Agreements Act of 1979, as amended (19 U.S.C. 2511–18).

In the final determination, CBP concluded that the assembly and attachment of a lead wire to the U.S. origin Electroencephalogram (EEG) Cutaneous Electrodes by crimping or gluing in China is not a substantial transformation. Therefore, the last substantial transformation of the Rhythmlink Electroencephalogram (EEG) Cutaneous Electrode product occurs in the United States.

Section 177.29, CBP Regulations (19 CFR 177.29), provides that notice of final determinations shall be published in the Federal Register within 60 days of the date the final determination is issued. Section 177.30, CBP Regulations (19 CFR 177.30), provides that any party-at-interest, as defined in 19 CFR 177.22(d), may seek judicial review of a final determination within 30 days of publication of such determination in the Federal Register.

Rhythmlink Electroencephalogram disposable EEG Electrode products.

The product comes in varying lengths/styles and the end user can customize the color of the connecting wire. The electrodes’ function is common to all lengths and is unchanged by the color of the connecting wire. There are three EEG electrode products that have common construction and function: the Disposable Slim Cup, the Disposable Deep Cup, and Disposable Webb.

Rhythmlink conducts all engineering and design of the EEG electrodes in the United States. The actual production and manufacture of the cutaneous electrodes is outsourced to a third party subcontractor located in the United States. The single-source manufacturer supplies the finished EEG electrodes to Rhythmlink, marked “Country of Origin: USA.” The manufacturer must further certify that, “This uniform silver chloride coating applied to precision molded products enhances the mechanical and electrical performance of the finished electrode products so they can meet or exceed applicable AAMI Standards.”

The fully assembled, packaged end product for medical use consists of five elements: the cutaneous electrode, the lead wire, a miniscule amount of crimp or glue, a heat shrink tube, and packaging. The subcontractor-supplied cutaneous electrodes are shipped from the United States to China where a lead wire is attached. You state that the lead wire acts as an electrical conductor that transfers low voltage electrical signals from the electrode to medical diagnostic...
equipment. The lead wire used in the product is a commercially available 26-gauge twisted copper wire comprising 19 strands of 38-gauge copper wire with medical-grade PVC covering (in a total of 25 color options). The Korean supplier of this wire, cuts the wire, crimps a socket pin, and attaches a connector to one end of the wire and then ships the wire to China. Neither the wire nor the connectors are proprietary and are common electrical materials.

In China, to support certain optional user preferences, the EEG electrodes are either attached to the lead wire of Korean origin, using a crimp produced in the United States or China. Crimp is a mix of tin, copper and nickel and represents only a tiny portion of the product’s cost. Alternatively, the process will utilize a German conductive adhesive glue, which is a mix of silver and epoxy and also represents a very small percentage of the product’s cost. The lead wire is crimped or glued to the electrode. The crimping process takes roughly five seconds (six operators can professionally crimp 6,000 products in a day). The alternative gluing process takes roughly 20 seconds (six operators can professionally glue 1,500 products in a day). Next, a heat shrink from either the United States or Japan is used to cover the joint. The heat shrink tube is an off-the-shelf product and undergoes simple assembly through crimping or gluing and includes attaching a lead wire to the electrode, adding a heat shrink and protective cover, and packaging. In HQ H296072, the subdermal needle electrodes of U.S. origin were attached by soldering in China. CBP held that the stimulating probes of the subdermal needle electrodes were not substantially transformed by the Chinese processing.

For products used in medical-related applications, we have held that no substantial transformation occurs when the critical components which impart the essential character of the product subsequently undergo simple assembly and processing. In HQ H296072, dated July 13, 2018, CBP considered the processing of a subdermal needle electrode. The processing was quite similar to the processing that the electrodes undergo in this case, and included attaching a lead wire to the electrode, adding a heat shrink and protective cover, and packaging. In HQ H296072, the subdermal needle electrodes of U.S. origin were attached by soldering in China. CBP held that the stimulating probes of the subdermal needle electrodes were not substantially transformed by the Chinese processing. 

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the crimping and gluing require only a low level of skill and technology. The crimping process takes roughly five seconds to perform, while the alternative gluing process takes roughly 20 seconds to complete. The remaining processing of the Product, consisting of cleaning and drying (spin and convention drying), adding the heat shrink cover, and inserting the Product into the plastic pouch and cardboard packaging are likewise simple, minor, and low-skill operations. Therefore, we find that the name, character, and use of the cutaneous electrode remain unchanged after the lead wire and other components are attached in China. As such, the U.S. origin cutaneous EEG electrodes which are processed in China by attaching a lead wire and being covered with a heat shrink, are not substantially transformed. Accordingly, for purposes of government procurement, we find that the last substantial transformation of the product is in the United States.

HOLDING:

Based on the information provided, the last substantial transformation of the self-adhesive cutaneous EEG electrode product occurs in the United States.

Notice of this final determination will be given in the Federal Register, as required by 19 C.F.R. § 177.29. Any party-at-interest other than the party which requested this final determination may request, pursuant to 19 C.F.R. § 177.30, that CBP reexamine the matter anew and issue a new final determination. Pursuant to 19 C.F.R. § 177.31, any party-at-interest may, within 30 days after publication of the Federal Register notice referenced above, seek judicial review of this final determination before the Court of International Trade.

Sincerely,

Craig T. Clark
Acting Executive Director, Regulations and Rulings, Office of Trade

[FR Doc. 2019–11373 Filed 5–30–19; 8:45 am]

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service


AGENCY: Fish and Wildlife Service, Interior.

ACTION: Notice of availability.

SUMMARY: We, the U.S. Fish and Wildlife Service, announce the availability of a final environmental impact statement (EIS) and a final habitat conservation plan (HCP) addressing the Skookumchuck Wind Energy Project (project) in Lewis and Thurston Counties, Washington. The Skookumchuck Wind Energy Project LLC (applicant) is requesting an incidental take permit (ITP) covering the take of one threatened species listed under the Endangered Species Act, and two non-listed federally protected species (collectively referred to as covered species) likely to be caused by the operation of the project over a 30-year period. The HCP describes the steps the applicant will take to minimize, mitigate, and monitor incidental take of the covered species. The final EIS has been prepared in response to the ITP application, in accordance with the requirements of the National Environmental Policy Act of 1969 (NEPA; 42 U.S.C. 4321 et seq.). The applicant is seeking an ITP authorizing take of the following covered species: Marbled murrelet (Brachyramphus marmoratus), bald eagle (Haliaeetus leucocephalus), and golden eagle (Aquila chrysaetos). The murrelet is listed as threatened under the ESA. Bald and golden eagles are not listed under the ESA, but are protected under the Bald and Golden Eagle Protection Act (BGEPA; 16 U.S.C. 668–668d).

If issued, the ITP would authorize take of the covered species that may occur as a result of their collision with project wind turbines, and as a result of the applicant carrying out site management and maintenance activities over the 30-year permit term. The applicant is not seeking ITP coverage for the construction phase of the project, which includes, without limitation, the construction of roads and turbine pads, and the erection of 38 commercial wind turbines, transmission lines, and meteorological towers. The applicant is also not seeking ITP coverage for the decommissioning of project facilities. The applicant anticipates completing project construction prior to implementation of the HCP.

The HCP describes the anticipated amount of take of each covered species, and the steps the applicant will implement to minimize and mitigate the impacts of that taking. The HCP also describes the life history and ecology of